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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,198	11/27/2001	Anders Bjorling	P01,0434	9390

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EXAMINER

SCHAETZLE, KENNEDY

ART UNIT PAPER NUMBER

3762

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/995,198	Applicant(s) BJORLING ET AL. ch	
	Examiner Kennedy Schaetzle	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7,9,11-14,22,23,27-31,56 and 57 is/are rejected.
- 7) ☒ Claim(s) 3-5,8,10,15-21,24-26 and 32-55 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/12/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 1 is objected to because of the following informalities: a typographical error appears to have been made when copying claim 1 (note the word "lacing" on line 5 as opposed to the previous version of the claim and its use of the word "placing"). Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 6, 11, 12, 22, 23, 27-29, 56 and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Glace (Pat. No. 5,158,092).

Regarding claim 1, Glace discloses a method wherein a plurality of electrodes (1, 2) at a tip of a cardiac lead (6) are placed in contact with cardiac tissue so that all of the electrodes are simultaneously in substantially fixed contact with the tissue. Individual unipolar electrical signals are obtained that exhibit a time relationship relative to each other (note Fig. 5). The time relationship is analyzed to obtain an analysis result (note for example col. 2, lines 18-46), and a signal is generated indicating a cardiac rhythm abnormality dependent upon said analysis result. In this case, the examiner considers the determination of the emergence point of the tachycardia to be an indication of a cardiac rhythm abnormality. The examiner also considers the electrical signals obtained by the electrodes to be unipolar in nature by virtue of the fact that each electrode produces an independent electrical signal (see Fig. 5 wherein electrode one produces signal 23, electrode two produces signal 24, and so on). If

electrodes one and two were combined in a bipolar arrangement, each pair would result in one signal.

Regarding claim 22, comments made above in the rejection of claim 1 apply here as well. Although Glace does not specifically refer to a QRS detector, the examiner considers the detection circuitry of Glace to be capable of detecting the QRS signal by virtue of the fact that it can detect ventricular activation signals.

Regarding claims 56 and 57, as argued above, the examiner considers the Glace reference to relate to unipolar signals. As a consequence, one unipolar signal would necessarily be obtained for each electrode making the number of unipolar signals equal the number of electrodes.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glace (Pat. No. 5,158,092).

Concerning claim 7, Glace does not elaborate on what aspect of the unipolar electrical signal is identified in order to determine the time relationship between signals. Fig. 5 appears to show that the rising edge of the activation signal is employed to determine the fiducial point from which phase measurements are calculated (note also col. 6, lines 12 and 13). In any event, those of ordinary skill in the art would have considered the exact point at which to base measurement on to be a matter of obvious design. Clearly both maximum slew rate and maximum negative derivative are old and well-known parameters useful in determining valid signals and more specifically, rising and falling edges. Any parameter useful in filtering out noise or spurious signals and allowing one to

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accurately obtain a landmark point from which to base measurement on, would have therefore been considered obvious by any ordinarily skilled artisan.

Similarly for claim 9, it is old and well-known in the cardiac signal processing arts to determine the slope of a signal and act on any signal that meets a set threshold indicative of a valid slope and thus a valid signal.

6. Claims 13, 14, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glace in view of Desai (Pat. No. 5,433,198).

Regarding claims 13 and 14 and claims with similar limitations, although Glace discloses an arrangement wherein the electrodes are disposed about the periphery of a disc sans a center electrode, those of ordinary skill in the art would have recognized the exact arrangement to be a matter of obvious design as long as the basic concept of the invention (i.e., allowing determination of the phase differences between electrodes as a result of the depolarization vector) was not interfered with. Desai disclose a related system wherein such an arrangement is incorporated (note for example Fig. 2B). To include a center electrode as shown by Desai to allow one to pinpoint the origin of a tachyarrhythmia such as disclosed in col. 10, lines 10-34 would have therefore been considered a matter of obvious design given their known use in related systems.

Allowable Subject Matter

7. Claims 15-21 and 32-55 are allowed.

With reference to claim 15, the prior art does not disclose or suggest a teaching for modifying any reference to include the steps of storing a detection pattern as a template and comparing subsequently obtained detections to the template and generating a signal indicating a cardiac rhythm abnormality dependent upon the comparison result.

A related comment applies to claim 32.

8. Claims 3-5, 8, 10 and 24-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

9. Applicant's arguments filed April 2, 2004 have been fully considered but they are not persuasive.

The applicants argue that the Glace reference is concerned exclusively with bipolar sensing –not unipolar sensing as required by the present invention's claims. The applicants refer to definitions of unipolar and bipolar arrangements and state that the examiner is not at liberty to disregard well-known and well-understood meanings. The examiner contends, however, that he is not giving any special meaning to the terms "unipolar" and "bipolar." The examiner accepts the general well-known definitions of these terms, but asserts that such art-recognized definitions do not conflict with the interpretation that Glace discloses unipolar sensing.

On page 20 of the Remarks, the applicants state that Figs. 1a and 1b of the Glace reference illustrate the probes that are used to obtain the signals in the Glace reference that are analyzed to determine cardiac rhythm abnormalities. The examiner agrees. The applicants further state that each of the probes clearly has two electrodes numbered 1 and 2, and that Fig. 1a shows an epicardial probe and Fig. 1b shows an endocardial catheter. Again the examiner agrees. The applicants then state that in all instances, the signals that are analyzed are obtained between or across electrodes 1 and 2. The examiner disagrees with this conclusory statement. It is unclear where in the reference the applicants have gleaned this assertion. The applicants refer to the paragraph beginning at col. 5, line 28 and state that despite the paragraph beginning at col. 5, line 53 which states that the signals 23, 24, 26 and 27 shown in Fig. 5 are produced respectively from sensors 1, 2, 1' and 2', it is clear that the electrodes are always being considered in pairs and thus the signals 23, 24, 26 and 27 (Fig. 5) are obtained from electrode pairs rather than from individual electrodes. Simply because sensor 1 is grouped with sensor 2 and sensor 1' is grouped with sensor 2' does not inherently mean that bipolar sensing must be occurring between the sensors. The "pairing" of sensors merely relates to the grouping of

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signals in order to ascertain phase shifts (see col. 5, lines 53-56). The signal from sensor 1(1') is compared or paired with the signal from sensor 2(2') to obtain the phase shift signal 25(26) shown in Fig. 5. It is unclear why unipolar signals cannot be compared or paired in this manner and why such a pairing from the applicants' standpoint necessitates bipolar signals. Glace explicitly states that the probe is composed of at least one assembly of two sensors (col. 2, lines 10 and 11). Figs. 1a and 1b show the probe in its simplest form (i.e., one assembly of two sensors). In col. 3, lines 1 and 2, Glace discloses that each assembly provides two signals combined in one phase shift signal. If in its simplest form the sensors 1 and 2 (i.e., electrodes 1 and 2) shown in Figs. 1a and 1b were bipolar, then it is unclear how a phase shift could ever be determined since such a determination of phase shift requires two independent signals. In other words, if the ring and tip electrodes shown for example in Fig. 1b were operating in a bipolar manner, then only one signal would be produced, begging the question: where does one obtain the required second signal so that a phase shift can be determined?

With reference to the argument concerning the use of azimuth angles, the use of such angles are only a trigonometric convenience to ascertain the direction and sense of the depolarization and have nothing to do with whether unipolar and bipolar sensing is employed. While the term can be associated with a bipolar electrode arrangement, this is not to say that the word can only be used to describe bipolar sensing arrangements. The azimuth is merely an imaginary line. A zero phase shift between signals sensed at each respective location simply means that the depolarization wave front is traveling at an angle perpendicular to the axis and thus reaches both electrodes at the same time. A maximum phase shift occurs when the wave front is traveling in a direction parallel to the axis and hits one electrode first followed by the other. Wave fronts at other angles produce phase shifts less than the maximum.

Regarding the applicants' argument that Fig. 8 makes it clear that even if the probes 1 and 2 are considered separately, each of the probes consists of two

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electrodes which feed signals into respective amplifiers, the examiner wishes to point out that use of the word *probe* to describe elements 1 and 2 is inaccurate. Elements 1 and 2 are actually sensors –not probes. As stated above, a probe in its simplest embodiment is composed of at least one assembly of two sensors (col. 2, lines 10 and 11). Therefore sensor 1 and sensor 2 in Fig. 8 actually are a part of a single probe such as shown in Figs. 1a and 1b. Sensor 1 in Fig. 8 may for example represent the ring electrode 1 in Fig. 1b, and the sensor 2 in Fig. 8 may represent the tip electrode 2 in Fig. 1b. As stated on page 50 of the “Basic Aspects of Cardiac Pacing” reference submitted by the applicants, The term unipolar pacing/sensing is technically a misnomer, as both bipolar and unipolar configurations require an anode and a cathode to complete the electrical circuit, with the anode in the case of a unipolar arrangement being the indifferent electrode of the pulse generator housing or other large surface area electrode. The highly simplified diagram shown in Fig. 8 could therefore just as likely represent signals taken between electrodes in a unipolar system (e.g., tip/housing and ring/housing) and not between electrodes (e.g., ring/tip) in a bipolar arrangement.

Given the above reasoning, the examiner therefore disagrees with the applicants’ contention that the Glace reference is *exclusively* concerned with bipolar sensing and that the signal analysis proceeds based on signals obtained in a bipolar manner.

Regarding the applicants’ argument that the signals obtained in the Glace reference are not analyzed to identify a cardiac rhythm abnormality, the examiner considers this to be a moot point since the applicants are not claiming the identification of a cardiac rhythm abnormality. Claim 1 simply requires generating a signal *indicating* a cardiac rhythm abnormality –not identifying it. Webster’s defines the word “indicate” to mean “...to direct attention to; point to or point out...” Clearly a signal pertaining to the direction of a cardiac rhythm abnormality is a signal that directs attention or points to the abnormality. The examiner is not at liberty to read non-existent limitations into the claims.

Even if the applicants were to amend the claim to incorporate the diagnosis of cardiac rhythm abnormalities and successfully argue or amend to obviate the rejection under Glace, it is doubtful that such a response would make the claims allowable over the prior art of record. The examiner wishes to draw the applicants' attention to the Bardy et al. reference which discriminates between tachycardia and fibrillation using bipolar or unipolar electrode arrangements to ascertain fiducial points and determine time relationships therebetween.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Note the discussion of Bardy et al. in the text above. DeCote, Jr. shows in Fig. 2 a differential amplifier used with both bipolar and unipolar electrode arrangements.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on 9:30 -6:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-0851. The fax

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phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
July 23, 2004



KENNEDY SCHAEZLE
PRIMARY EXAMINER